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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,533	07/29/2003	Ronald J. Thompson	Thompson-10A	6052
7590 Donald N. Halgren 35 Central St. Manchester, MA 01944		10/26/2007	EXAMINER LANDSMAN, ROBERT S	
			ART UNIT 1647	PAPER NUMBER
			MAIL DATE 10/26/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



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## DETAILED ACTION

### ***1. Formal Matters***

- A. The Amendment filed 10/11/07 has been entered into the record.
- B. Claims 1-4 are pending and are the subject of this Office Action.

### ***2. Specification***

- A. The objection to the specification is withdrawn in view of Applicants' amendments to the Brief Description of the Figures.

### ***3. Claim Objections***

- A. The objection to the claims has been withdrawn in view of Applicants' amendments.
- B. The specification is objected to since the Brief Description of Figure 7 should recite "stomach" instead of "stmach."
- C. Claims 1-4 are objected to since it is unclear if claim 1 is drawn to all three of stimulating, depleting AND blocking or if it is drawn to one of stimulating, depleting OR blocking.

### ***4. Claim Rejections - 35 USC § 112, first paragraph - enablement***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

- A. Claims 1-4 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 2-3 of the Office Action mailed 6/11/07. Applicants argue that it is the inventor's belief that the specification is enabling. This argument has been considered, but is not deemed persuasive. First, as noted in the above statute under 35 USC 112, first paragraph,

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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The claims recite a method of reducing appetite in a mammal by one or all of three ways – stimulating Ghrelin release, depleting Ghrelin stores, blocking Ghrelin activity in the brain or bloodstream. Applicant has disclosed how Ghrelin would apparently act on the stomach and on appetite, which, based on Applicants' specification, seems to be well-known in the art (see Applicants' discussion of the prior art). However, Applicant is claiming stimulating, depleting and/or blocking Ghrelin. While it may be apparent from the discussion of the prior art that these mechanisms may reduce appetite, Applicant has not provided any "full, clear, concise and exact terms" of how to make and use the invention.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Applicant has not provided any discussion, guidance or working examples of how to stimulate Ghrelin release. It appears from the specification that all that is known is that Ghrelin regulates appetite. However, no means of stimulating this hormone are described. The issue is similar for depleting Ghrelin stores and blocking Ghrelin activity. The Applicant has not clearly and concisely demonstrated how to perform such a method. No guidance or working examples of any method of doing so, including any compounds that act on Ghrelin, is disclosed. Applicant's Figures only describe a general mechanism of drug absorption using only a hypothetical drug. Given this lack of guidance and working examples it would not be predictable to the artisan how to practice the claimed invention. Not only is no "best mode" described, but, respectfully, no mode is described except for a number of generalizations.

If the invention is truly novel, then the Applicant does deserve some breadth; however, at this point, the claims and specification have not satisfactorily enabled the invention. Though the prior art may not teach the claimed mechanism, that does not default patentability to the instant application in lack of an enabling specification.

#### ***5. Claim Rejections - 35 USC § 112, first paragraph – written description***

A. Claims 1-4 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 3-4 of the Office Action mailed 6/11/07. Applicants argue that it is the inventor's belief that the specification is enabling. This argument has been considered, but is not deemed persuasive for the reasons discussed above under enablement.

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**6. Claim Rejections - 35 USC § 112, second paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- A. Claims 1-2 remain objected to for the reasons already of record on page 4 of the Office Action mailed 6/11/07. Applicants have not amended the claims, nor addressed this argument.

**7. Conclusion**

- A. No claim is allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**Advisory information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on M-F 10 AM – 7 PM (eastern).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao at 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Robert Landsman, Ph.D.  
Primary Examiner  
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